REMARKS:

• Status of the Claims

Claims 34-36, 38-40 and 42-54 are pending in the present application. Claims 35 and 36 have been amended and claims 47 through 54 have been added. No new subject matter has been added by these amendments because claims 35 and 36 have merely been rewritten in the independent form and claims 47 through 54 are identical to claims 38-40 and 42-46 except that the presently added claims depend from claim 35 rather than claim 34.

• Claim Objections

In the Office Action dated February 25, 2004, the Examiner objected to claims 35 and 36 as being dependent upon a rejected base claim. Applicant has addressed this concern by amending claims 35 and 36 into independent form; thus, claims 35 and 36 are now free from any rejection and should be allowable. In this regard, Applicant has also added claims 47-55, each of which depend from and include each and every limitation of claim 35. As such, claims 47-55 are allowable as well.

• Issues under 35 U.S.C. §§ 102 and 103

In the Office Action dated February 25, 2004, the Examiner rejected claims 34, 38-40 and 42-46 under 35 U.S.C. § 102(b) or 103(a) based on Heller *et al.*, Proc. Natl. Acad. Sci. 94, 2150-2155 (March 1997) and further rejected claims 34, 38-40 and 42-46 under 35 U.S.C. § 102(b) or 103(a) based on DeRisi, *et al.*, Nat. Gen. 14 (4), 457-460 (Dec. 1996). Both Heller *et al.* and DeRisi *et al.* describe microarrays and related assays.

With regard to a rejection under 102(b), it is well-settled that for a *prima facie* case to be established, the cited prior art reference must disclose each and every limitation found in a claim against which it is cited because "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdgall Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. Likewise, with regard to a rejection under 103(a), it must be established that the prior art reference, or a combination of references, teaches or suggest each and every limitation of the claim. *See e.g., In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (C.C.P.A. 1970).

With regard to both Heller *et al.* and DeRisi, *et al.*, the Examiner admits that each reference fails to "explicitly teach that all of the genes present in their microarray are under the control of the same regulatory element," but argues that this limitation is "inherent to the teaching of [each reference] in that all of the genes present in their array[s] are under the control of promoters (i.e., same regulatory element)." Office Action of February 25, 2004, Paragraph 4 and Paragraph 5.

In order "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." See *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981). Further, "[i]n relying on inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied prior art." See *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Also relevant in the instant case is what the Federal Circuit has established as not rising to the level of inherency. For example, the Federal Circuit has stated that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See *In re Rijckaert*, 28 USPQ2d 195, 1957 (Fed. Cir. 1993) (reversing a rejection where inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art). Also, the Federal Circuit has stated that the mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Robertson*, 49 USPQ2d 1949, 1950-51.

As mentioned above, the Examiner states that all genes are under control of a promoter and, in liking promoters to the claimed "regulatory element," argues the inherency of the of the claim limitation: "wherein expression of all of the genes is under control of the same regulatory element." Applicant respectfully disagrees with the Examiner's characterization of the promoters of the various genes of the Heller array or the promoters of the various genes of the DeRisi array as being the "same regulatory element" or even as being "regulatory elements."

A promoter is merely a site to which RNA polymerase will bind and initiate transcription, not a site that is a regulatory element to which an enhancer or repressor may bind. Although a promoter may be *associated with* nucleic acid sequences that positively or negatively influence the expression of a gene to which an enhancer or repressor binds, a promoter is not in and of itself one of these regulatory elements. As such, neither the promoters of the genes of the Heller array, nor the promoters of the genes of the DeRisi array, nor the promoters of the genes of any array may be properly be characterized as "regulatory elements."

Furthermore, the various promoters of the Heller array or the DeRisi array may not

properly be characterized as the "same regulatory element." With regard to Heller *et al.*, the genes are not selected based on their regulatory elements; rather, they are known human genes of probable significance in rheumatoid arthritis and human genes from the peripheral blood lymphocyte library, selected without regard to the regulatory elements of their non-coding regions. *See* Heller *et al.* at 2150-51. Likewise, the genes selected in DeRisi *et* al. are not selected based on the regulatory elements of their non-coding regions. *See* DeRisi *et al.* at 459-60. As such, it is most unlikely that the regulatory elements of the each of the various genes of the Heller arrays or the DeRisi arrays contain the *same defined nucleotide bases to which an enhancer or a repressor may bind.* In any event, these references certainly contain no suggestion that the various genes of the described arrays may contain the *same defined nucleotide bases to which an enhancer or a repressor may bind* in their non-coding regions. Furthermore, as mentioned above, the mere fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that characteristic. See *In re Rijckaert*, 28 USPQ2d at 1957.

In this regard, because both 102(b) and 103(a) require a showing that each and every limitation of a claim is taught or suggested by the prior art reference, Applicant requests that the rejections based on both Heller *et al.* and DeRisi *et al.* be withdrawn with respect to claim 34 and the associated dependent claims 38-40 and 42-46.

In light of the foregoing amendments and remarks, Applicant respectfully requests allowance of all claims now pending in this Application.

Respectfully submitted,

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